

REMARKS

Claims 1-44 are presently pending in this Application. In the instant Amendment, Applicants have canceled Claims 2, 4-6, 17-19, 21-24, and 26-44, without prejudice, have amended Claims 1, 3, 8-9, 11-12, 16, 20, and 25, and have added new Claims 45-53. Support for amended Claims 2, 4-6, 17-19, 21-24, and 26-44, as well as new Claims 45-53 can be found generally throughout the instant Specification, and particularly in and Claims 1-44 as filed.

Claim Objections

Claims 1, 6-16, 20-22 and 25-26 have been objected to under 37 CFR 1.75(d)(1) as being in improper form because the Claims state an improper Markush Group. The Examiner has asserted that compounds included within a Markush group must:

- (1) share a common utility; and
- (2) share a substantial structural feature disclosed as being essential to that utility.

The Examiner has asserted that while SEQ ID NO:2 and SEQ ID NO:8 recited in Claims 1, 6-16, 20-22, 25 and 26 may share the common utility of being MIF1, the Specification does not disclose that the compounds share a substantial structure feature disclosed as being essential to that utility. Hence, in the Examiner's opinion, because a substantial feature is not disclosed as being essential to the utility that is common to the claimed species, the claim states an improper Markush group.

In response, Applicants initially submit that Claims 6, 21, 22, and 26 have been canceled, without prejudice. Hence, this objection with respect to these Claims is MOOT.

Moreover, Applicants respectfully submit that amended Claim 1 does not contain a Markush grouping. Hence, this objection with respect to Claims 1, 7-16, 20, and 25 and 26 should be removed.

The Examiner has also objected to Claims 1, 20 and 26 because the Examiner believes "MEKK" and "FHA" recited in the Claims should be spelled out followed by the abbreviations in parenthesis. In response, Applicants have amended Claims 1 and 20 to recite these full names followed by their abbreviations. Support for this amendment of Claims 1 and 20 can be found on page 7, lines 31-32 of the instant Specification, and on page 1, lines 22-23 of the instant Specification. In light of these amendments, this objection should be removed.

The Invention is Enabled

Claim 1, with dependent Claims 6-16, 20-22, 25, and 26 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed Invention at the time the instant Application was filed. In making this rejection, the Examiner has asserted that Claim 1(a) is drawn to a DNA encoding MIF1 that can be amplified using specific primers; claim 1(b) is drawn to a DNA that hybridizes under undefined stringent conditions to SEQ ID NO:1; claim 1(c) is drawn to a DNA encoding splice and allelic variants of SEQ ID NO:1; and Claim 1(d) is drawn to a DNA encoding a polypeptide which specifically binds to an antibody against residues 16-28 of SEQ ID NO:8. It is the Examiner's belief though that hybridization conditions are not defined, and there are no limitations on the structure of a gene amplified using the specific primers. Thus, it is the opinion of the Examiner that the structures of MIF1 and DNA encoding thereof encompassed by the

claimed genera include species which are widely variant in structure and function. In light of these assertions, the Examiner believes many structurally and functionally unrelated DNAs are encompassed within the scope of these Claims, including partial DNA sequences in addition to the single species disclosed of the claimed genus, SEQ ID NO:1. Furthermore, the Examiner has asserted the instant Specification fails to disclose any identifying characteristics or properties of the members of the claimed genus, and also fails to provide any structure: function correlation present in all members of the claimed genus.

The Examiner has also asserted that the instant Specification allegedly does not describe mutational sites that exist in nature, and there is not description of how the structure of SEQ ID NO:1 relates to the structure of any naturally occurring alleles. It is the position of the Examiner that the general knowledge in the art concerning alleles does not provide any indication of how one allele is representative of unknown alleles. Moreover, the Examiner believes the nature of alleles is such that they are variant structures, and in the present state of the art, the structure of one does not provide guidance to the structure of others. The Examiner also has asserted that the instant Specification does not describe any splice variant other than SEQ ID NO:1.

In light of the above, the Examiner believes the description of SEQ ID NO:2 and a DNA encoding thereof of SEQ ID NO:1 is insufficient to be representative of the attributes and feature of the entire genus. Consequently, it is the position of the Examiner that one skilled in the art cannot reasonably conclude that Applicants had possession of the claimed Invention at the time the instant Application was filed.

Applicants respectfully traverse these rejections. Amended Claim 1 is directed towards *inter alia*, an isolated nucleic acid molecule that encodes an MIF1 that comprises the amino acid

sequence of SEQ ID NO:2. It is not directed towards a DNA encoding MIF1 that can be amplified using specific primers, a DNA that hybridizes under undefined stringent conditions to SEQ ID NO:1, a DNA encoding splice and allelic variants of SEQ ID NO:1, or a DNA encoding a polypeptide which specifically binds to an antibody against residues 16-28 of SEQ ID NO:8. Indeed SEQ ID NO:2 is clearly set forth in the instant Specification. Hence, it is respectfully submitted that amended Claim 1 is clearly enabled, and this rejection should be withdrawn.

The Invention is Definite

Claim 1, with dependent Claims 6-16, 20-23, 25 and 26 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that Applicants regard as the Invention. The Examiner has asserted that Claim 1 is indefinite because the term "MEKK interacting FHA protein (MIF1)" does not clearly define the protein function. In particular, the Examiner believes that the interaction between two proteins can be indirect or direct. The Examiner believes that if it is direct, the effect of such binding produces, such as inhibitory, stimulatory, etc. should be defined. Thus, it is the position of the Examiner that without defining the interaction, there is no way of knowing what the metes and bounds are of the claim. Moreover, citing page 1, lines 22-30 of the instant Specification for support, the Examiner believes that without knowing which MEKK is interacting, the metes and bounds of the claims are indefinite.

Furthermore, the Examiner has asserted the phrase "stringent conditions" recited in claim 1(b) is indefinite, because, in the Examiner's opinion, said conditions can mean different conditions in different experiments. Consequently, the Examiner believes DNAs of different structures will hybridize under different conditions rendering the scope of the claims

unascertainable.

In addition, the Examiner has asserted that Claim 1(d) recites the phrase "specifically binds to an antibody." The Examiner believes though that many different polypeptides may be construed as specifically binding to an antibody. It is the position of the Examiner that without a definition of this term, there is no way of knowing which polypeptides are encompassed by the claims.

Applicants respectfully traverse this rejection. Amended Claim 1 is directed towards an isolated nucleic acid encoding an upstream serine threonine kinase (MEKK) interacting forkhead associated (FHA) protein (MIF1) that comprises the amino acid sequence of SEQ ID NO:2. Clearly the "metes and bounds" of amended Claim 1, i.e., an isolated nucleic acid that encodes the amino acid sequence of SEQ ID NO:2, are readily definite and understood by one of ordinary skill in this art. Moreover, amended Claim 1 does not recite phrases such as "stringent conditions", and "specifically binds to an antibody." Hence, it is respectfully submitted that amended Claim 1 as well as Claims dependent thereto are definite, and this rejection is obviated.

The Invention is Novel

Claims 1-3, 6-16, 20-23, 25 and 26 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Ren *et al.* The Examiner has asserted that Ren *et al.* teach a protein of 462 amino acids that comprises SEQ ID NO:2 of the instant Invention (page 735, Figure 1). The Examiner also believes that Ren *et al.* teach a DNA comprising SEQ ID NO:1 of the instant Invention that encodes the protein, as well as a mouse ortholog thereof. Furthermore, the Examiner believes Ren *et al.* teach vectors and host cells comprising the DNA, and its expression. It is the Examiner's opinion that the DNA taught by Ren *et al.* is a naturally occurring variant of SEQ ID

NO:1 of the instant Invention, will hybridize to SEQ ID NO:1 of the instant Invention, and encodes a polypeptide that specifically binds to an antibody to which SEQ ID NO:2 binds.

Finally, the Examiner has asserted that Ren *et al.* name the protein described therein as "58 kDa microspherule protein (MSP58)" and demonstrate its interaction with nucleolar protein p120. In the opinion of the Examiner, regardless of whether the interaction disclosed by Ren *et al.* ultimately represents the same function as is discussed in the instant Application, the Examiner believes the protein remains the same. Hence, it is the position of the Examiner that Ren *et al.* disclosure of protein MSP58 and the DNA that encodes the protein anticipate Claims 1-3, 6-16, 20-23 and 25-26.

Applicants respectfully traverse this rejection. Initially, Applicants respectfully point out to the Examiner that in the instant Amendment, Claims 2, 4-6, 17-19, 21-24, and 26-44 have been canceled, without prejudice. Thus, this rejection with respect to Claims 2, 6, 21-23, and 26 is MOOT. Furthermore, Applicants respectfully submit that the subject matter of amended Claims 1, 3, 8-9, 11-12, 16, 20, and 25, and new Claims 45-53 is novel.

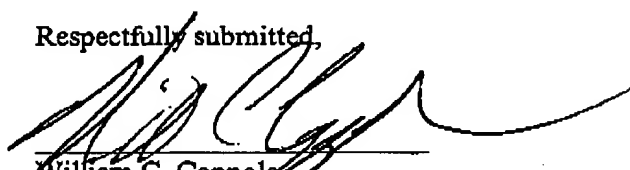
Fees

No additional fees are believed to be necessitated by the foregoing Response. However, should this be erroneous, authorization is hereby given to charge Deposit Account No. 18-1982 for any underpayment, or credit any overages.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,



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